UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/147,443	01/21/99	MORELL	A P63221US0

HM12/0911

JACOBSON PRICE HOLMAN & STERN
400 SEVENTH STREET NW
WASHINGTON DC 20004

EXAMINER	
DECLOUX A	
ART UNIT	**PAPER NUMBER**
1644	24

DATE MAILED: 09/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/147,443	Morell
Examiner	**Art Unit**
DeCloux, Amy	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Jun 22, 2001

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-21 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-21 are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 1-10, 14-17 and 19-20 in Paper No. 23, filed June 22, 2001, is acknowledged.

2. However, upon further review it is noted that the term Group I encompasses approximately 32 patentable distinct polypeptides with 32 distinct SEQ ID Nos. Searching all said sequences is an undue search burden , especially in terms of the computer based sequence searches at the patent office. encompasses patentably distinct methods as defined in the instant specification. Furthermore, it is noted that group I contains nucleotide and polypeptide sequences. Polypeptides and nucleotides are independent and distinct (they are materially different substances) and are to be restricted one from the other.

Because of the patentably distinct polypeptides and patentably distinct DNA sequences encompassed by Group I, a new restriction of the instant application which includes a re-restriction of Group I, claims 1-10, 14-17 and 19-20, is imposed.

3. Applicant's submission of the instant application as a 371 is acknowledged, however Claim 11 does not provide a technical feature that is distinguished over the prior art, as evidenced by Seigel (Annals N.Y. Acad. Sciences, (1995), Volume 764, pages 547-558) who teach a process for preparing recombinant polypeptides capable of forming antigen binding structures by making cDNA from the RNA of cells from individuals capable of forming RH antibodies, and using said cDNA to create a phage display library, which is then screened and DNA encoding the Fab fragment is then obtained (see entire article including Figures 1 and 2). Therefore, the instant invention lacks Unity of Invention.

4. A restriction is required under 35 USC 121 and 372 between one of the following groups:

I. Claims 1-5, 14-17 and 19-21, drawn to the embodiment of a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD1-40-VH and LD1-40-VL, and pharmaceutical composition thereof, classified in Class 530, subclass 387.1, and class 514, subclass 15,

II. Claims 1-5, 14-17 and 19-21, drawn to the embodiment of a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD1-52-VH and LD1-52-VL, and a pharmaceutical composition thereof, classified in Class 530, subclass 387.1, and class 514, subclass 15,

III. Claims 1-5, 14-17 and 19-21, drawn to the embodiment of a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD1-84-VH and LD1-84-VL, and a pharmaceutical composition thereof, classified in Class 530, subclass 387.1, and class 514, subclass 15,

IV. Claims 1-5, 14-17 and 19-21, drawn to the embodiment of a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD1-110-VH and LD1-110-VL, and a pharmaceutical composition thereof, classified in Class 530, subclass 387.1, and class 514, subclass 15,

V. Claims 1-5, 14-17 and 19-21, drawn to the embodiment of a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD1-117-VH and LD1-117-VL, and a pharmaceutical composition thereof, classified in Class 530, subclass 387.1, and class 514, subclass 15,

VI. Claims 1-5, 14-17 and 19-21, drawn to the embodiment of a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD2-1-VH and LD2-1-VL, and a pharmaceutical composition thereof, classified in Class 530, subclass 387.1, and class 514, subclass 15,

VII. Claims 1-5, 14-17 and 19-21, drawn to the embodiment of a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD2-4-VH and LD2-4-VL, and a pharmaceutical composition thereof, classified in Class 530, subclass 387.1, and class 514, subclass 15,

VIII. Claims 1-5, 14-17 and 19-21, drawn to the embodiment of a polypeptide pair capable of forming antigen binding structures , having the Identification numbers LD2-5-VH and LD2-5-VL, and a pharmaceutical composition thereof, classified in Class 530, subclass 387.1, and class 514, subclass 15,

IX. Claims 1-5, 14-17 and 19-21, drawn to the embodiment of a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD2-10-VH and LD2-10-VL, and a pharmaceutical composition thereof, classified in Class 530, subclass 387.1, and class 514, subclass 15,

X. Claims 1-5, 14-17 and 19-21, drawn to the embodiment of a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD2-11-VH and LD2-11-VL, and a pharmaceutical composition thereof, classified in Class 530, subclass 387.1, and class 514, subclass 15,

XI. Claims 1-5, 14-17 and 19-21, drawn to the embodiment of a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD2-

14-VH and LD2-14-VL, and a pharmaceutical composition thereof, classified in Class 530, subclass 387.1, and class 514, subclass 15,

XII. Claims 1-5, 14-17 and 19-21, drawn to the embodiment of a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD2-17-VH and LD2-17-VL, and a pharmaceutical composition thereof, classified in Class 530, subclass 387.1, and class 514, subclass 15,

XIII. Claims 1-5, 14-17 and 19-21, drawn to the embodiment of a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD2-20-VH and LD2-20-VL, and a pharmaceutical composition thereof, classified in Class 530, subclass 387.1, and class 514, subclass 15,

XIV. Claims 1-5, 14-17 and 19-21, drawn to the embodiment of a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD1-6-17-VH and LD1-6-17-VL, and a pharmaceutical composition thereof, classified in Class 530, subclass 387.1, and class 514, subclass 15,

XV. Claims 1-5, 14-17 and 19-21, drawn to the embodiment of a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD1/2-6-3--VH and LD1/2-6-3-VL, and a pharmaceutical composition thereof, classified in Class 530, subclass 387.1, and class 514, subclass 15,

XVI. Claims 1-5, 14-17 and 19-21, drawn to the embodiment of a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD1/2-6-33-VH and LD1/2-6-33-VL, and a pharmaceutical composition thereof, classified in Class 530, subclass 387.1, and class 514, subclass 15,

XVII. Claims 6-10 and 18, drawn to the embodiment of DNA sequences coding for a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD1-40-VH and LD1-40-VL , and a process for preparing said antibodies, classified in Class 536, subclass 23.1 and Class 435, subclasses 69.1, 252.3 and 320.1,

XVIII. Claims 6-10 and 18, drawn to the embodiment of DNA sequences coding for a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD1-52-VH and LD1-52-VL, and a process for preparing said antibodies, classified in Class 536, subclass 23.1 and Class 435, subclasses 69.1, 252.3 and 320.1,

XIX. Claims 6-10 and 18, drawn to the embodiment of DNA sequences coding for a polypeptide pair capable of forming antigen binding structures, having the

Identification numbers LD1-84-VH and LD1-84-VL, and a process for preparing said antibodies, classified in Class 536, subclass 23.1 and Class 435, subclasses 69.1, 252.3 and 320.1,

XX. Claims 6-10 and 18, drawn to the embodiment of DNA sequences coding for a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD1-110-VH and LD1-110-VL, and a process for preparing said antibodies, classified in Class 536, subclass 23.1 and Class 435, subclasses 69.1, 252.3 and 320.1,

XXI. Claims 6-10 and 18, drawn to the embodiment of DNA sequences coding for a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD1-117-VH and LD1-117-VL, and a process for preparing said antibodies, classified in Class 536, subclass 23.1 and Class 435, subclasses 69.1, 252.3 and 320.1,

XXII. Claims 6-10 and 18, drawn to the embodiment of DNA sequences coding for a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD2-1-VH and LD2-1-VL, and a process for preparing said antibodies, classified in Class 536, subclass 23.1 and Class 435, subclasses 69.1, 252.3 and 320.1,

XXIII. Claims 6-10 and 18, drawn to the embodiment of DNA sequences coding for a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD2-4-VH and LD2-4-VL, and a process for preparing said antibodies, classified in Class 536, subclass 23.1 and Class 435, subclasses 69.1, 252.3 and 320.1,

XXIV. Claims 6-10 and 18, drawn to the embodiment of DNA sequences coding for a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD2-5-VH and LD2-5-VL, and a process for preparing said antibodies, classified in Class 536, subclass 23.1 and Class 435, subclasses 69.1, 252.3 and 320.1,

XXV. Claims 6-10 and 18, drawn to the embodiment of DNA sequences coding for a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD2-10-VH and LD2-10-VL, and a process for preparing said antibodies, classified in Class 536, subclass 23.1 and Class 435, subclasses 69.1, 252.3 and 320.1,

XXVI. Claims 6-10 and 18, drawn to the embodiment of DNA sequences coding for a polypeptide pair capable of forming antigen binding structures, having the

Identification numbers LD2-11-VH and LD2-11-VL, and a process for preparing said antibodies, classified in Class 536, subclass 23.1 and Class 435, subclasses 69.1, 252.3 and 320.1,

XXVII. Claims 6-10 and 18, drawn to the embodiment of DNA sequences coding for a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD2-14-VH and LD2-14-VL, and a process for preparing said antibodies, classified in Class 536, subclass 23.1 and Class 435, subclasses 69.1, 252.3 and 320.1,

XXVIII. Claims 6-10 and 18, drawn to the embodiment of DNA sequences coding for a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD2-17-VH and LD2-17-VL, and a process for preparing said antibodies, classified in Class 536, subclass 23.1 and Class 435, subclasses 69.1, 252.3 and 320.1,

XXIX. Claims 6-10 and 18, drawn to the embodiment of DNA sequences coding for a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD2-20-VH and LD2-20-VL, and a process for preparing said antibodies, classified in Class 536, subclass 23.1 and Class 435, subclasses 69.1, 252.3 and 320.1,

XXX. Claims 6-10 and 18, drawn to the embodiment of DNA sequences coding for a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD1-6-17-VH and LD1-6-17-VL, and a process for preparing said antibodies, classified in Class 536, subclass 23.1 and Class 435, subclasses 69.1, 252.3 and 320.1,

XXXI. Claims 6-10 and 18, drawn to the embodiment of DNA sequences coding for a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD1/2-6-3--VH and LD1/2-6-3-VL, and a process for preparing said antibodies, classified in Class 536, subclass 23.1 and Class 435, subclasses 69.1, 252.3 and 320.1,

XXXII. Claims 6-10 and 18, drawn to the embodiment of DNA sequences coding for a polypeptide pair capable of forming antigen binding structures, having the Identification numbers LD1/2-6-33-VH and LD1/2-6-33-VL, and a process for preparing said antibodies, classified in Class 536, subclass 23.1 and Class 435, subclasses 69.1, 252.3 and 320.1,

XXXIII. **(Formerly II)** Claims 11-13 and 18, drawn to a process for preparing and/or selecting recombinant polypeptides capable of forming antigen binding

structures, classified in Class 435, subclass 7.2,

NOTE: Regarding Groups I-XVI (Claims 1-5, 14-17 and 19-21): The table recited in claim I and 14 (and dependent claims 2-5 and 16-17 and 19-21), recites SEQ ID NO:s that are nucleotides, while the invention claims a polypeptide product. Applicant is requested to clarify.

5. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

6. Groups I-XXXII are unique products. They differ with respect to their structures and physicochemical properties and are therefore patentably distinct.

7. Group XXXIII and Groups I-XVI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product, the recombinant polypeptides capable of forming antigen binding structures with specificity for Rhesus D antigens and complete anti-Rhesus D antibodies can be made from hybridomas generated by the fusion of spleen cells from immunized mammals and non immunoglobulin secreting cell lines, as well as the recited method using a phage display library.

8. Groups XVII-XXXII and Group XXXIII are unrelated products and method and are therefore patentably distinct.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

11. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers **other than elections** related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located In Crystal Mall 1. The faxing of such papers must conform with the notice published In the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner
Group 1640, Technology Center 1600
September 10, 2001

David A Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182